PATENT SPECIFICATION

DRAWINGS ATTACHED

831,401

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Adhesive Product.

COMPLETE SPECIFICATION

I, BENJAMIN B. BLACKFORD, a citizen of the United States of America, of 203, Amboy Avenue, Metuchen, New Jersey, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed to be particularly described in and by the following statement:

This invention relates to adhesive suture strips and more particularly to improved adhesive suture strips for coapting the edges of a wound, cut, or body incision and fixing the edges in position so that they may heal properly.

To minimize scar formation and to lessen patient discomfort, certain types of body cuts, wounds and incisions made during surgical operations are closed with adhesive suture strips instead of by sewing with suture threads of cotton, catgut, linen, and the like. A typical adhesive suture strip is generally in the form of an elongated strip of flexible material having its ends coated on one surface with a tacky, pressure-sensitive adhesive and an intermediate uncoated portion between the ends. The adhesive coating is usually covered with a facing member of crinoline or similar material which is removed to expose the adhesive coating to place the suture strip in condition for use. When in position on the body, a suture strip extends transversely across the wound with the adhesive coated ends secured to the skin on each side of the wound and the intermediate uncoated portion bridging the wound.

To close a wound with an adhesive suture strip, one adhesive end of the strip is pressed against the skin on one side of the wound, the strip is pulled across the wound and the edges of the wound are urged together. The other adhesive end of the strip is then pressed into contact with the skin on the opposite side of the wound. As the strip is being applied, tensile stresses are imposed upon it. These tensile stresses tend to cause the strip to loosen and become detached, and it is necessary, therefore, that the strip adhere tenaciously during application. Once applied, it must remain in position from two to ten days without loosening. If the strip does not adhere tenaciously directly upon application, or does not remain adherent during the required period and becomes detached prematurely, it is ineffective and the wound will open. Adhesive suture strips heretofore available were unsatisfactory in these respects. They loosened readily, particularly at the corners, and could be detached easily.

In attempts to overcome these difficulties with earlier adhesive suture strips, the adhesive side of the strip was pressed firmly against the body and the pressure maintained for a period of time. However, in many instances this procedure did not solve the problem because the adhesiveness of the strips was inherently inadequate. Another technique was then developed to increase the adhesive effectiveness of the suture strips. This technique is referred to as "flaming," and involves placing the adhesive coating on the strip in contact with an open flame, such as the flame of an alcohol burner, thereby increasing the tackiness of the adhesive. The technique is still used today despite its limitations. It is unsatisfactory, however, because it is inconvenient and time consuming when time may be short. Also, considerable care must be exercised because the strip may be "overflamed" and perhaps burned, or the adhesiveness of the adhesive material destroyed or otherwise significantly altered.

The present invention eliminates these and other disadvantages of earlier adhesive suture strips by providing an adhesive suture strip which adheres instantaneously and tenaciously to the skin of the body upon application, which remains in intimate adhesive contact with the skin for sufficient time to permit the wound to heal, which can with

(Price 3s. 6d.)

stand substantial tensile stress without loosening, and which can be applied simply, rapidly, and efficiently.

In the drawings:

Fig. 1 is a perspective view of an adhesive suture strip incorporating the invention;

Fig. 2 is a top plan view of the strip;

Fig. 3 is a view of Fig. 2 with the facing member removed;

Fig. 4 is an enlarged sectional view of Fig. 1 taken along line 4—4;

Fig. 5 illustrates the early steps in applying the suture strip to a wound on the forearm of an individual; and

Fig. 6 illustrates the final steps of drawing together the wound edges with the suture strip.

In accordance with the present invention, an adhesive suture strip for coapting the edges of a wound comprises a non-extensible, flexible backing member having wide ends and a narrow intermediate portion adapted to bridge the wound, said intermediate portion presenting a non-adherent surface on one side of said backing member, said ends having tacky, pressure-sensitive adhesive coatings sufficient to cover unevenesses if any, of the surface of the underlying backing member, on the same side of said backing member, at least one facing member covering said adhesive coatings and of which at least one surface is the smooth surface of a film made of an organic film forming material which is substantially inert to the adhesive, said smooth surface being in such close intimate contact with the area of the adhesive coating that substantially no air is occluded at the interface and the underlying adhesive coating has a smooth surface corresponding to that of the film, said film being releasable by said adhesive when the facing member is removed so that the adhesive surface is left substantially smooth.

Referring to the drawings, there is shown an elongated backing member 1 of flexible, relatively nonextensible material formed with wide, generally rectangular-shaped ends 2 and a narrow intermediate portion 3 between the ends. A surface of each of the wide ends on the same side of the backing member is coated with a tacky pressure-sensitive adhesive 4. The narrow, intermediate portion, which bridges the wound, is nonadherent so that it will not stick to the wound. If desired, the backing member itself, nonadherent and uncoated with adhesive, may constitute the intermediate portion. Preferably, the intermediate portion is covered with nonadherent layer, such as a thin flexible plastic film 5, to present a nonsticking surface which contacts the wound. In this form of the invention, the narrow intermediate portion of the backing member is also coated with the adhesive applied to the ends of the backing member and the thin, flexible plastic film is placed on the adhesive and is adhesively secured in position.

The backing member is made from a material which is relatively nonextensible so that it will not stretch appreciably under the tension imposed when the suture strip is applied to the body and so that it will hold the edges of the wound in position once they are coapted. Backings of woven textile material, such as a woven cotton fabric with a mesh of about 80 x 80 threads per inch, are satisfactory for this purpose. The backings may be waterproofed by coating or impregnating with a waterproofing compound, such as plasticised vinyl chloride, ethyl cellulose, or with other compounds well-known for this purpose. Plastic films, such as polyethylene terephthalate, which are substantially nonstretchable, may also be used. Stretchable plastic films, such as vinyl films, may be used in combination with a nonstretching component as by forming a laminate of the stretchable plastic film and a woven fabric of the type noted above.

Many materials may be used to provide the narrow intermediate portion of the strip with the desired nonadherent surface. Example are films one-half to three mils thick of "Cellophane," (Registered Trade Mark) ethylene glycol terephthalate, cellulose acetate, kraft papers coated with such compounds as ethyl cellulose, polyethylene, and polystyrene, and laminates thereof formed in various combinations.

To provide the adhesive suture strip of the invention with the tenacity of adhesion required when the suture strip is applied to the body, the strip has the property of instantaneous adhesion. This important feature of the invention is attained by covering the adhesive coating of the strip with a facing member comprising a film of organic material having a surface in contact with the coating. To attain the property, four basic relationships must be observed: (1) The film must present a smooth and continuous surface; (2) It must be substantially inert with respect to the adhesive mass; (3) It must be in intimate contact with the underlying adhesive coating to the exclusion of air over substantially the entire surface thereof to impart to the underlying adhesive coating at its interface with the facing member, the smooth surface characteristics of the film; and, (4) It must be releasable by the particular adhesive mass used so that when the facing member is removed, the adhesive will not be separated from its backing and the smooth surface characteristics of the adhesive which exists at the interface of the adhesive and the surface of the facing member before the latter is removed will be substantially unimpaired.

Materials which can be used as facing members include plastic films, alone or in

laminar combination with other components such as paper, and paper impregnated with materials which will form a coating on the surface of the paper of the desired type. Suitable films include cellophane, those made from cellulose acetate, vinyl chloride resins, copolymers of vinyl chloride and vinyl acetate or vinylidene chloride. The impregnated papers include kraft papers impregnated with ureaformaldehyde resin, melamine and formaldehyde resin. The papers may be coated with a plastic, such a polyethylene, or may be laminated to a plastic film with a smooth, continuous, even surface Release agents may be incorporated in or on the facing to promote releasability of the facing member from the adhesive mass when it is stripped therefrom.

The particular requirements of the facing material and the adhesive mass, and the method of applying the facing material are more fully described in Patent Specification No. 754,848 which relates to surgical dressings.

The facing member may be a single length of material overlying the adhesive side of the strip. However, as illustrated in Figures 1 and 4, it is preferably in two parts, 6 and 7, each of which overlies one adhesive coating on one end of the strip and extends over the narrow intermediate portion of the strip to form overlapping tabs 8 and 9 which can be readily grasped to strip each part from the adhesive. The facing members may, in conjunction with other components, also serve as a wrapper for the suture strip. Alternatively, the facing members may be independent of any wrapper.

Most conventional pressure-sensitive adhesive masses may be used to form the adhesive coating such as those which have a base of natural or synthetic material, including styrene, butadiene and isobutylene. The adhesive mass may be based on other polymers, such as polyalkylacrylate. A satisfactory adhesive mass is composed of polyisobutylene, preferably with an average molecular weight (Staudingor) of about 100,000 componded with effective amounts of tackifier, plasticizer, etc. In addition, the composition of the adhesive mass and its plasticity may be modified in accordance with well-known practices to include tackifiers, plasticizers, etc., and to vary the characteristics of the mass as desired. The adhesive mass may be calendered on the backing, spread on with solvents, or otherwise applied. It should be sufficient to cover any unevenesses present in the backing such as are found in woven backing.

In manufacturing the suture strip, the adhesive is placed on the backing member in any suitable manner; e.g. calendering, solvent spreading, the plastic film is placed on the narrow intermediate portion of the strip and the facing member or members then laid on top of the adhesive. The combination so formed is passed between rollers which are adjusted to impose sufficient force to compress the facing member into intimate contact with the surface of the adhesive mass to exclude any voids or air bubbles so that the mass surface will acquire the smooth, even surface characteristics of the surface of the facing member.

To demonstrate the comparative effectiveness of an adhesive suture strip prepared in accordance with the invention and a suture strip of conventional form having a facing member of crinoline, a series of tests was conducted. The tests particularly illustrate the extent of tensile stress to which suture strips prepared in accordance with the invention may be subjected in use before becoming detached.

Six one-inch wide sterilizable strips having backing members of waterproofed cotton fabric of 80 x 80 mesh were each coated with a tacky, pressure-sensitive adhesive mass containing 32% natural rubber; 32% pigments; 5% lanolin; and 31% polyterpene resin of 70°C. melting point. The adhesive surfaces of three of the strips were faced with crinoline in accordance with convention practices by placing the crinoline on the adhesive and pressing the crinoline into adhesive contact with the adhesive. The remaining three strips were provided with cellulose acetate-paper laminate facing members in accordance with the invention.

The strips so formed were sterilized by placing in sealed containers containing 10% ethylene oxide for 6 hours at a temperature of 160°F. After sterilizing, the facing members were removed from each of the strips. Eeach strip was laid on a lacquered metal plate to provide an area one inch by two inches in adhesive contact with the plate. At the end of five minutes, a shear adhesion test was performed by applying tension to the strips in the direction of the plane of the plates until they separated from the plates. The test was performed with a commercially available strain gauge tensile tester. A jaw separating speed of twelve inches per minute was used. The average shear adhesion of three tests on the strips having a crinoline facing was forty ounces. The average of three tests on strips prepared in accordance with the invention and having the cellulose acetate-paper laminate facing member was one-hundred-twenty-eight ounces.

A second series of tests was conducted to compare the initial adherence of the suture strip of the invention with a suture strip of conventional form. The strips tested were of the same construction as those used in the tests above and were sterilizsed in the same manner. In these tests, a one-quarter square inch adhesive area of each of the strips was

laid on a glass plate and a one-hundred-twenty-five gram weight was immediately placed on top of the strip for thirty seconds. The weight was then removed and tension was applied immediately to the strip in the plane of the glass until the strip was pulled off the glass plate in shear. The average of four tests run on adhesive suture strips of conventional form faced with crinoline was one pound. The average of four tests on suture strips prepared in accordance with the invention was four and one-quarter pounds.

The first test shows that after being permitted to remain in adhesive contact with a surface for a period of time, a suture strip of the invention can withstand stresses in shear more than three times greater than those which may be applied to a suture strip faced with crinoline. The last test demonstrates that directly after the adhesive suture strip of the invention is applied, it can withstand shear stresses more than four times greater than those which may be imposed upon adhesive suture strips of conventional form.

After an adhesive suture strip is applied to a wound under tension and the wound edges are coapted, it is necessary that the wound edges to be held in that position for sufficient time to permit the wound to heal. If the suture strip moves appreciably, or becomes detached before the wound has healed, the wound may open again. Earlier suture strips were generally of angular configuration and presented corners and edges which loosened readily. Once this occurred, the entire suture strip could be easily detached or would become sufficiently loosened to lose its effectiveness and to require its removal.

Premature detaching of the suture strip for the above reasons is substantially eliminated in accordance with the present invention by providing the suture strip with rounded corners thus causing the edges of the strip which meet at the corners to merge smoothly into each other along curved lines. As shown in Figure 2 and 3, the outside corners 10 of the suture strip are rounded and the sides 11 of the strip merge smoothly into the side edges defining the narrow, intermediate portion 3 to impart a generally dumbell-shaped configuration to the suture strip. The suture strip is devoid of sharp angles of the type which may be easily lifted out of adhesive attachment with the body.

The suture strip of the invention is applied to the wound by removing the facing members 6 and 7, placing an adhesive end of the strip on the skin on one side of the wound with the narrow intermediate portion 3 bridging the wound, as shown in Figure 5. The edges of the wound are drawn together to close the wound and the opposite end of the strip is then adhesively secured to the skin on the other side of the wound to complete application of the strip.

WHAT I CLAIM IS:

1. An adhesive suture strip for coapting the edges of a wound comprising a non-extensible, flexible backing member having wide ends and a narrow intermediate portion adapted to bridge the wound, said intermediate portion presenting a non-adherent surface on one side of said backing member, said ends having tacky, pressure-sensitive adhesive coatings sufficient to cover unevenesses if any, of the surface of the underlying backing member, on the same said side of said backing member, at least one facing member covering said adhesive coatings and of which at least one surface is the smooth surface of a film made of an organic film forming material which is substantially inert to the adhesive, said smooth surface being in such close intimate contact with the area of the adhesive coating that substanially no air is occluded at the interface and the underlying adhesive coating has a smooth surface corresponding to that of the film, said film being releasable by said adhesive when the facing member is removed so that the adhesive surface is left substantially smooth.

2. An adhesive suture strip according to Claim 1, wherein the outside corners of the strip are rounded and the edges of the strip which meet at the corners merge smoothly into each other along curved lines.

3. An adhesive suture strip according to claim 1 or 2, wherein said intermediate portion is coated with the same adhesive as the ends of the backing member and a plastic film is stuck on the intermediate portion by the adhesive, the exposed surface of the film being non-adherent.

4. An adhesive suture strip according to any of claims 1—3 wherein the backing member is a dumbbell-shaped sheet or strip.

5. An adhesive suture strip according to any of the preceding claims, wherein said facing member or members present finger gripping tabs for removing said facing member.

6. An adhesive suture strip according to Claim 5 wherein the finger gripping tabs of the facing members overlie the narrow intermediate portion of the backing member.

7. An adhesive suture strip for coapting the edges of a wound constructed and arranged substantially as described with reference to the accompanying drawings.

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831,401 COMPLETE SPECIFICATION
1 SHEET

This drawing is a reproduction of the Original on a reduced scale.

Fig. 1.

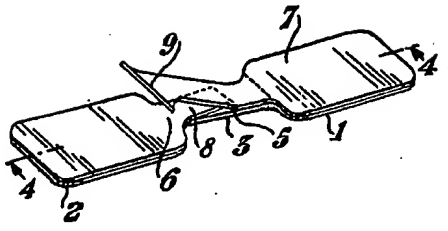

Fig. 2.

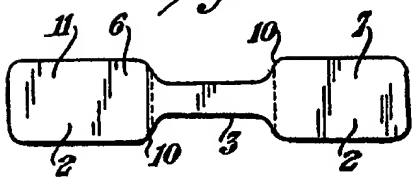

Fig. 3.

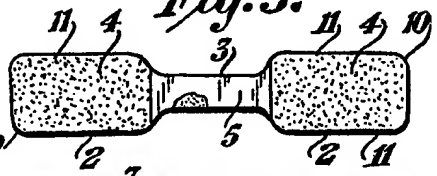

Fig. 4.

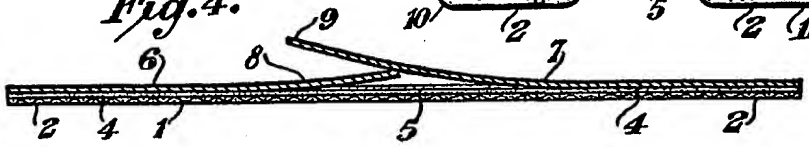

Fig. 6.

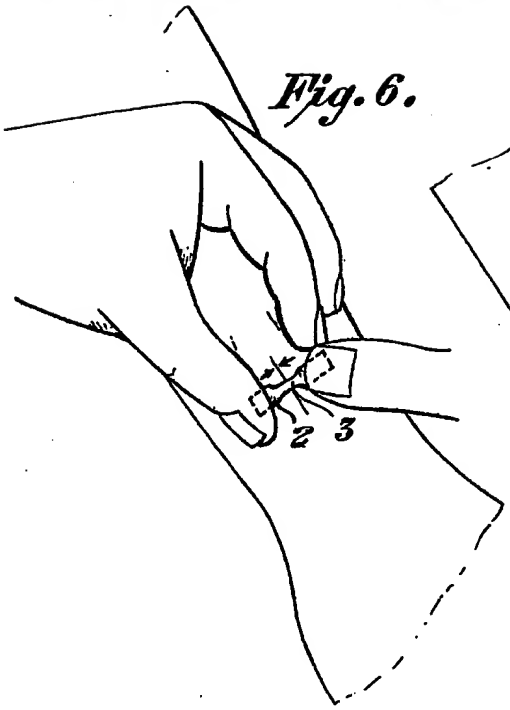

Fig. 5.